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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,104	08/17/2000	Walter Birchmeier	0107-028P	5225

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/15/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,104

Applicant(s)

BIRCHMEIER ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Claim 35 is an improper dependent claim because the claim is cited as being dependent from claim 35. To advance prosecution, claim 35 is read as being dependent from claim 34.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claims 1-5 and 9-15, drawn to an agent or a peptide which affects the interaction between β -catenin and LEF-1/TCF-4 transcription factors, wherein the agent is a part of peptide sequences from LEF-1/TCF-4 transcription factors or their variants, classified in class 514, subclasses 13 and 14.
 - II. Claims 16 and 17, drawn to a method for using peptides of claims 9-15 for treating tumors, wherein the peptides are coupled with a second peptide, classified in class 514, subclass 12.
 - III. Claim 18, drawn to a method for using peptides of claims 9-15 for treating tumors, wherein the peptides are coupled with a second peptide and are modified to increase the stability, e.g., peptidomimetics, classified in class 514, subclass 12.
 - IV. Claim 19, drawn to a method for using peptides of claims 9-15 for treating tumors, wherein the peptides are coupled with a second peptide and the carbon skeleton is substituted by carbon skeletons with the same arrangement of functional groups, e.g., non-peptidomimetics, classified in class 514, subclass 12.
 - V. Claims 1-8 and 20-28, drawn to an agent or a peptide which affects the interaction between β -catenin and LEF-1, TCF-4, APC, conductin or E-cadherin, wherein the agent is from the armadillo domain of β -catenin or one of specific interaction domains of β -

Art Unit: 1653

catenin towards LEF-1, TCF-4, APC, conductin or E-cadherin, classified in class 514, subclass 12.

VI. Claim 29, drawn to a method of using peptidomimetics modified from peptides of claims 20-28, classified in class 514, subclass 12.

VII. Claim 29, drawn to a method of using non-peptidomimetics modified from peptides of claims 20-28, classified in class 514, subclass 12.

VIII. Claim 30, drawn to a method of using the peptides of claims 20-28 to build up agents for treating tumors, tissue and organic damage, classified in class 514, subclass 12.

IX. Claim 31, drawn to a method of using the peptides of claims 20-28 to screen the substances which specifically inhibit the interaction of β -catenin with LEF-1, TCF-4, APC, conductin or E-cadherin, classified in class 514, subclass 12.

X. Claim 32, drawn to a method of using the peptides of claims 20-28 to inhibit the interaction of β -catenin with LEF-1, TCF-4, APC, conductin or E-cadherin, classified in class 514, subclass 12.

XI. Claim 33, drawn to a method of using the peptides of claims 20-28 to promote the interaction of β -catenin with LEF-1, TCF-4, APC, conductin or E-cadherin for regeneration of tissue or organs, classified in class 514, subclass 12.

XII. Claim 34, drawn to a method of ELISA for screening of substance libraries for compounds which affect the interaction of β -catenin with LEF-1, TCF-4, APC, conductin or E-cadherin for treating tumors, classified in class 514, subclass 12.

Art Unit: 1653

XIII. Claim 35, drawn to a method of ELISA for screening of substance libraries for compounds in claims 9-15 to identify the substance for treating tumors, regeneration of tissue and organs, classified in class 514, subclass 12.

XIV. Claim 35, drawn to a method of ELISA for screening of substance libraries for compounds in claims 20-28 to identify the substance for treating tumors, regeneration of tissue and organs, classified in class 514, subclass 12.

Should Invention I, II, III, IV or XIII be elected, applicant is required to select one peptide sequence from claims 9-15. Each peptide sequence, absent factual data to the contrary, is a distinct peptide. This is not species election.

Should Invention V, VI, VII, VIII, IX, X, XI, XII or XIV be elected, applicant is required to select one peptide from claims 20-28. Each peptide sequence, absent factual data to the contrary, is a distinct peptide. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

The product of Invention I and the methods of Invention II, III, IV, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Invention II, III, IV, and XIII are alternative processes of use of the peptide of Invention I.

The product of Invention I is distinct from the product of Invention V because they have different modes of operation, different functions and produce different effects. In the instant case the peptide of Invention I is a part of peptide sequences from LEF-1/TCF-4 transcription

Art Unit: 1653

factors and affects the interaction between β -catenin and LEF-1/TCF-4 transcription factors, while the product of Invention V is from β -catenin and would affect not only the interaction of β -catenin to LEF-1/TCF-4, but also the interaction of β -catenin to APC, conductin or E-cadherin.

The product of Invention I is distinct from the methods of Invention VI-XII and XIV because the product of Invention I can be neither made by nor used in the methods of Invention VI-XII and XIV.

The product of Invention V is distinct from the methods of Inventions II-IV and XIII because the product of Invention V can be neither made by nor used in the methods of Inventions II-IV and XIII.

The product of Invention V and the methods of Inventions VI-XII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VI-XII and XIV are alternative processes of use of the peptide of Invention V.

The methods of Inventions II-IV and VI-XIV are distinct from each other because the methods of Inventions II-IV and XIII use the product of Invention I while the methods of Inventions VI-XII and XIV use the product of Invention V, and the method steps and outcomes are wholly different among Inventions II-IV and VI-XIV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because inventions I-XIV require different searches but are not co-extensive, examination of these

Art Unit: 1653

distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Karen Cochrane Carlson (Pat)
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

Application/Control Number: 09/641,104

Page 7

Art Unit: 1653

March 11, 2002